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(54) Temporary distal embolic protection device

(57) A guidewire apparatus for use during percutaneous catheter interventions, such as angioplasty or stent deployment. A protection element comprising a filter or an occluder is mounted near the distal end of a steerable guidewire, which guides a therapeutic catheter. The guidewire apparatus comprises a hollow shaft

movably disposed about a core wire and, optionally, a slippery liner interfitted there between. The shaft and core wire control relative displacement of the ends of the protection element, causing transformation of the protection element between a deployed configuration and a collapsed configuration.

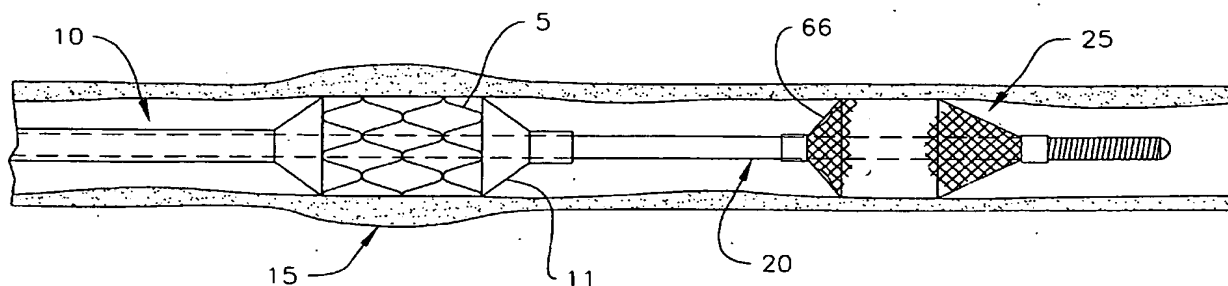


FIG. 1

EP 1 344 502 A2

Description

[0001] This patent application is a continuation-in-part of U.S. Patent Application Ser. No. 09/918,441 to Douk *et al.* filed July 27, 2001, which is a continuation-in-part of U.S. Patent Application Ser. No. 09/824,832 to Douk *et al.* filed April 3, 2001 entitled "Temporary Intraluminal Filter Guidewire and Methods of Use."

FIELD OF THE INVENTION

[0002] The present invention relates generally to intraluminal devices for capturing particulate in the vessels of a patient. More particularly, the invention relates to a filter or an occluder for capturing emboli in a blood vessel during an interventional vascular procedure, then removing the captured emboli from the patient after completion of the procedure. Furthermore, the invention concerns a filter or an occluder mounted on a guidewire that can also be used to direct an interventional catheter to a treatment site within a patient.

BACKGROUND OF THE INVENTION

[0003] A variety of treatments exists for dilating or removing atherosclerotic plaque in blood vessels. The use of an angioplasty balloon catheter is common in the art as a minimally invasive treatment to enlarge a stenotic or diseased blood vessel. When applied to the vessels of the heart, this treatment is known as percutaneous transluminal coronary angioplasty, or PTCA. To provide radial support to the treated vessel in order to prolong the positive effects of PTCA, a stent may be implanted in conjunction with the procedure.

[0004] Thrombectomy is a minimally invasive technique for removal of an entire thrombus or a sufficient portion of the thrombus to enlarge the stenotic or diseased blood vessel and may be accomplished instead of a PTCA procedure. Atherectomy is another well-known minimally invasive procedure that mechanically cuts or abrades a stenosis within the diseased portion of the vessel. Alternatively, ablation therapies use laser or RF signals to superheat or vaporize a thrombus within the vessel. Emboli loosened during such procedures may be removed from the patient through the catheter.

[0005] During each of these procedures, there is a risk that emboli dislodged by the procedure will migrate through the circulatory system and cause ischaemic events, such as infarction or stroke. Thus, practitioners have approached prevention of escaped emboli through use of occlusion devices, filters, lysing, and aspiration techniques. For example, it is known to remove the embolic material by suction through an aspiration lumen in the treatment catheter or by capturing emboli in a filter or occlusion device positioned distal of the treatment area.

BRIEF DESCRIPTION OF THE DRAWINGS

[0006] Features, aspects and advantages of the present invention will become better understood with reference to the following description, appended claims, and accompanying drawings where:

[0007] FIG. 1 is an illustration of a filter system in accordance with the invention deployed within a blood vessel;

[0008] FIG. 2 is an illustration of a filter system in accordance with the invention deployed within a portion of the coronary arterial anatomy;

[0009] FIG. 3 is an illustration of a prior art expandable mesh device, shown with the mesh in a collapsed configuration;

[0010] FIG. 4 is an illustration of a prior art expandable mesh device, shown with the mesh in a deployed configuration;

[0011] FIG. 5 is a longitudinal sectional view of a first guidewire embodiment in accordance with the invention;

[0012] FIG. 6 is a longitudinal sectional view of a second guidewire embodiment in accordance with the invention;

[0013] FIG. 7 is a cross-sectional view of the second guidewire embodiment taken along the lines 7 - 7 of FIG. 6;

[0014] FIG. 8 is a modified form of the cross-sectional view shown in FIG. 7;

[0015] FIG. 9 is another modified form of the cross-sectional view shown in FIG. 7;

[0016] FIG. 10 is an enlarged supplementary view of a portion of FIG. 8, which has been modified to illustrate alternative embodiments of the invention;

[0017] FIG. 11 is a longitudinal sectional view of a segment of a hollow shaft and liner in accordance with the invention;

[0018] FIG. 12 is a partially sectioned longitudinal view of a third guidewire embodiment in accordance with the invention; and

[0019] FIG. 13 is a partially sectioned longitudinal view of a fourth guidewire embodiment in accordance with the invention;

[0020] FIG. 14 is an alternative form of the fourth guidewire embodiment shown in FIG. 13.

SUMMARY OF THE INVENTION

[0021] The guidewire apparatus of the invention includes a protection element comprising a filter or an occluder mounted near the distal end of a steerable guidewire, which guides a therapeutic catheter. The guidewire apparatus comprises a hollow shaft movably disposed about a core wire and, optionally, a slippery liner interfitted there between. The shaft and core wire control relative displacement of the ends of the protection element, causing transformation of the protection element between a deployed configuration and a col-

lapsed configuration.

DETAILED DESCRIPTION OF THE INVENTION

[0022] The present invention is a guidewire apparatus for use in minimally invasive procedures. While the following description of the invention relates to vascular interventions, it is to be understood that the invention is applicable to other procedures where the practitioner desires to capture embolic material that may be dislodged during the procedure. Intravascular procedures such as PTCA or stent deployment are often preferable to more invasive surgical techniques in the treatment of vascular narrowings, called stenoses or lesions. With reference to FIGS. 1 and 2, deployment of balloon expandable stent 5 is accomplished by threading catheter 10 through the vascular system of the patient until stent 5 is located within a stenosis at predetermined treatment site 15. Once positioned, balloon 11 of catheter 10 is inflated to expand stent 5 against the vascular wall to maintain the opening. Stent deployment can be performed following treatments such as angioplasty, or during initial balloon dilation of the treatment site, which is referred to as primary stenting.

[0023] Catheter 10 is typically guided to treatment site 15 by a guidewire. In cases where the target stenosis is located in tortuous vessels that are remote from the vascular access point, such as coronary arteries 17 shown in FIG. 2, a steerable guidewire is commonly used. According to the present invention, a guidewire apparatus generally guides catheter 10 to treatment site 15 and includes a distally disposed protection element to collect embolic debris that may be generated during the procedure. Various embodiments of the invention will be described as either filter guidewires or occluder guidewires. However, it is to be understood that filters and occluders are interchangeable types of protection elements among the inventive structures disclosed. The invention is directed to embolic protection elements wherein relative movement of the ends of the protection element either causes or accompanies transformation of the element between a collapsed configuration and an expanded, or deployed configuration. Such transformation may be impelled by external mechanical means or by self-shaping memory (either self-expanding or self-collapsing) within the protection element itself. The protection element may be self-expanding, meaning that it has a mechanical memory to return to the expanded, or deployed configuration. Such mechanical memory can be imparted to the metal comprising the element by thermal treatment to achieve a spring temper in stainless steel, for example, or to set a shape memory in a susceptible metal alloy such as a nickel-titanium (nitinol) alloy.

[0024] Filter guidewires in accordance with the invention include distally disposed filter 25, which may comprise a tube formed by braided filaments that define pores and have at least one proximally-facing inlet

opening 66 that is substantially larger than the pores. Alternative types of filters may be used in filter 25, such as filter assemblies that include a porous mesh mounted to expandable struts. Optionally, adding radiopaque markers to filter ends 27, 29, as shown in FIG. 12, can aid in fluoroscopic observation of filter 25 during manipulation thereof. Alternatively, to enhance visualization of braided filter 25 under fluoroscopy, at least one of the filaments may be a wire having enhanced radiopacity compared to conventional non-radiopaque wires suitable for braiding filter 25. At least the majority of braiding wires forming filter 25 should be capable of being heat set into the desired filter shape, and such wires should also have sufficient elastic properties to provide the desired self-expanding or self-collapsing features. Stainless steel and nitinol monofilaments are suitable for braiding filter 25. A braiding wire having enhanced radiopacity may be made of, or coated with, a radiopaque metal such as gold, platinum, tungsten, alloys thereof, or other biocompatible metals that, compared with stainless steel or nitinol, have a relatively high X-ray attenuation coefficient. One or more filaments having enhanced radiopacity may be inter-woven with non-radiopaque wires, or all wires comprising filter 25 may have the same enhanced radiopacity.

[0025] In accordance with the invention, maintaining filter 25 in a collapsed configuration during introduction and withdrawal of filter guidewire 20 does not require a control sheath that slidably envelops filter 25. Thus, this type of device is sometimes termed as "sheathless." Known types of sheathless vascular filter devices are operated by a push-pull mechanism that is also typical of other expandable braid devices, as shown in FIGS. 3 and 4. Prior art expandable mesh device 30 includes core wire 32 and hollow shaft 34 movably disposed there about. Tubular mesh, or braid 36 surrounds core wire 32 and has a braid distal end fixed to core wire distal end 40 and a braid proximal end fixed to shaft distal end 41. To expand braid 36, core wire 32 is pulled and shaft 34 is pushed, as shown by arrows 37 and 39 respectively in FIG. 4. The relative displacement of core wire 32 and shaft 34 moves the ends of braid 36 towards each other, forcing the middle region of braid 36 to expand. To collapse braid 36, core wire 32 is pushed and shaft 34 is pulled, as shown by arrows 33 and 35 respectively in FIG. 3. This reverse manipulation draws the ends of braid 36 apart, pulling the middle region of braid 36 radially inward toward core wire 32.

[0026] Referring now to FIG. 5, in a first embodiment of the invention, filter guidewire 20 includes core wire 42 and flexible tubular tip member 43, such as a coil spring, fixed around the distal end of core wire 42. Thin wires made from stainless steel and/or one of various alloys of platinum are commonly used to make coil springs for such use in guidewires. Core wire 42 can be made from shape memory metal such as nitinol, or a stainless steel wire, and is typically tapered at its distal end. For treating small caliber vessels such as coronary

arteries, core wire 42 may measure about 0.15 mm (0.006 inch) in diameter.

[0027] In filter guidewire 20, hollow shaft 44 is movably disposed around core wire 42, and includes relatively stiff proximal portion 46 and relatively flexible distal portion 48. Proximal portion 46 may be made from thin walled stainless steel tubing, usually referred to as hypo tubing, although other metals, such as nitinol, can be used. Various metals or polymers can be used to make relatively flexible distal portion 48. One appropriate material for this element is thermoset polyimide (PI) tubing, available from sources such as HV Technologies, Inc., Trenton, GA, U.S.A. The length of distal portion 48 may be selected as appropriate for the intended use of the filter guidewire. In one example, portion 48 may be designed and intended to be flexible enough to negotiate tortuous coronary arteries, in which case the length of portion 48 may be 15 - 35 cm (5.9 - 13.8 inches), or at least approximately 25 cm (9.8 inches). In comparison to treatment of coronary vessels, adaptations of the invention for treatment of renal arteries may require a relatively shorter flexible portion 48, and neurovascular versions intended for approaching vessels in the head and neck may require a relatively longer flexible portion 48.

[0028] When filter guidewire 20 is designed for use in small vessels, shaft 44 may have an outer diameter of about 0.36 mm (0.014 inch). The general uniformity of the outer diameter may be maintained by connecting proximal portion 46 and distal portion 48 with lap joint 49. Lap joint 49 may use any suitable adhesive such as cyanoacrylate instant adhesives from Loctite Corporation, Rocky Hill, CT, U.S.A., or Dymax Corporation, Torrington, CT, U.S.A. Lap joint 49 can be formed by any conventional method such as reducing the wall thickness of proximal portion 46 in the region of joint 49, or by forming a step-down in diameter at this location with negligible change in wall thickness, as by swaging.

[0029] Expandable tubular filter 25 is positioned generally concentrically with core wire 42, and is sized such that when it is fully deployed, as shown in FIGS. 1 and 2, the outer perimeter of filter 25 will contact the inner surface of the vessel wall. The surface contact is maintained around the entire vessel lumen to prevent any emboli from slipping past filter 25. Cyanoacrylate adhesive may be used to secure filter distal end 27 to tip member 43, and to secure filter proximal end 29 near the distal end of shaft 44. As shown in FIGS. 12 and 13, radiopaque marker bands, such as platinum rings, can be incorporated into the adhesive joints securing filter ends 27, 29 respectively to tip member 43 and shaft 44. Filter 25 is deployed by advancing, or pushing shaft 44 relative to core wire 42 such that filter distal and proximal ends 27, 29 are drawn toward each other, forcing the middle, or central section of filter 25 to expand radially. Filter 25 is collapsed by withdrawing, or pulling shaft 44 relative to core wire 42 such that filter distal and proximal ends 27, 29 are drawn apart from each other, forcing the

middle, or central section of filter 25 to contract radially.

[0030] Transition sleeve 45 is fixed about core wire 42 and is slidably located within the distal end of flexible distal portion 48 of hollow shaft 44. Transition sleeve 45 may be made of polyimide tubing similar to that used in distal portion 48 and extends distally there from. By partially filling the annular space between core wire 42 and shaft 44, and by contributing additional stiffness over its length, sleeve 45 supports core wire 42 and provides a gradual transition in overall stiffness of filter guidewire 20 adjacent the distal end of shaft 44. Transition sleeve 45 is fixed to core wire 42 with adhesive such as cyanoacrylate, such that relative displacement between shaft 44 and core wire 42 causes corresponding relative displacement between shaft 44 and sleeve 45. The length and mounting position of sleeve 45 are selected such that sleeve 45 spans the distal end of shaft 44 regardless of the configuration of filter 25 and the corresponding position of shaft 44 relative to core wire 42. When constructed as described above, filter guidewire 20 provides the functions of a temporary filter combined with the performance of a steerable guidewire.

[0031] FIG. 6 depicts a second embodiment of the invention in which filter guidewire 120 incorporates a number of elements similar to the elements that make up filter guidewire 20. Such similar elements will be identified with the same reference numerals throughout the description of the invention. Filter guidewire 120 includes core wire 142 and flexible tubular tip member 43 fixed around the distal end of core wire 142, similar to the arrangement of guidewire 20, *supra*. Hollow shaft 144 is movably disposed around core wire 142 and is comparable, throughout its length, to relatively stiff proximal portion 46 of filter guidewire 20. Filter 25 is positioned generally concentrically with core wire 142. Filter distal end 27 is fixedly coupled to tip member 43, and filter proximal end 29 is fixedly coupled near the distal end of shaft 144.

[0032] Optionally, a portion of core wire 142 within the proximal end of shaft 144 has one or more bends 160 formed therein. The amplitude, or maximal transverse dimension of bends 160 is selected such that the bent portion of core wire 142 fits, with interference, within shaft 144. The interference fit provides sufficient friction to hold core wire 142 and shaft 144 in desired axial positions relative to each other, thereby controlling the shape of filter 25, as described *supra* with respect to filter guidewire 20.

[0033] In filter guidewire 120, liner 145 is interfitted as a low-friction axial bearing in the annular space between core wire 142 and shaft 144. With respect to the three coaxially arranged elements, the selected dimensions and the stack-up of dimensional tolerances will determine how liner 145 functions during the push-pull operation of core wire 142 within shaft 144.

[0034] For example, FIG. 7 depicts a cross-section of filter guidewire 120 in which there is radial clearance between liner inner surface 150 and core wire 142, and

there is also radial clearance between liner outer surface 151 and the inner wall of shaft 144. In this arrangement, liner 145 is radially free-floating in the annular space between core wire 142 and shaft 144. The length of liner 145 is selected such that it also "floats" axially along core wire 142. The axial movement of liner 145 along core wire 142 is limited proximally by a stop formed at the engagement of bends 160 with the inner wall of shaft 144. Tip member 43 limits the axial distal movement of liner 145 along core wire 142. The radial and axial flotation of liner 145 in filter guidewire 120 provides an axial bearing wherein the components with the lesser relative coefficient of friction can slide against each other. For example, if the coefficient of friction between liner inner surface 150 and core wire 142 is less than the coefficient of friction between liner outer surface 151 and the inner wall of shaft 144, then liner 145 will remain longitudinally fixed within shaft 144, and push-pull action will cause core wire 142 to slide within liner 145. Conversely, if the coefficient of friction between liner inner surface 150 and core wire 142 is greater than the coefficient of friction between liner outer surface 151 and the inner wall of shaft 144, then liner 145 will remain longitudinally fixed about core wire 142, and push-pull action will cause shaft 144 to slide over liner 145. The relative coefficients of friction for the movable components of the guidewire assembly may be designed-in by selection of materials and/or coatings, as will be described *infra*. Alternatively, the degree of sliding friction may result from unplanned events, such as the formation of thrombus on one or more component surfaces or embolic debris entering the annular space (s) there between.

[0035] FIG. 8 depicts a modified form of the cross-sectional view shown in FIG. 7 in which liner 145' is fitted against the inner wall of shaft 144, leaving radial clearance only between liner inner surface 150' and core wire 142. FIG. 9 depicts another modified form of the cross-sectional view shown in FIG. 7 in which liner 145" is fitted against core wire 142, leaving radial clearance only between liner outer surface 151' and the inner wall of shaft 144.

[0036] When filter guidewire 120 is designed for use in small vessels, shaft 144 may have an outer diameter of about 0.36 mm (0.014 inch), and core wire 142 may measure about 0.15 mm (0.006 inch) in diameter. Shaft 144, which can be made from hypo tubing, may have an inside diameter of about 0.23 mm (0.009 inch). For liner 145 to "float" in an annular space between core wire 142 and shaft 144 with such dimensions, liner outer surface 151 may measure about 0.22 mm (0.0088 inch) in diameter and liner inner surface 150 may measure about 0.18 mm (0.0069 inch) in diameter. Liner 145' does not require clearance around its outside diameter, because it is fitted against the inner wall of shaft 144. As compared to liner 145, liner 145' may have a greater wall thickness, and liner inner surface 150' may have a similar inner diameter of about 0.18 mm (0.0069 inch). Liner

145" does not require inside clearance because it is fitted against core wire 142. As compared to liner 145, liner 145" may also have greater wall thickness, and liner outer surface 151' may have a similar outer diameter of about 0.22 mm (0.0088 inch).

[0037] Liners 145, 145' and 145" may be formed of polymers selected to provide low coefficients of friction on their sliding surfaces. Typical of such polymers are polytetrafluoroethylene (PTFE), fluorinated ethylene-propylene (FEP), high-density polyethylene (HDPE), and various polyamides (nylons). Alternatively, liners 145, 145' and 145" may be formed of a material selected for physical properties other than a low coefficient of friction, i.e. stiffness or ability to be formed with tight dimensional tolerances. For such materials, a slippery coating, such as silicone, may be applied to the sliding surface (s) in order to achieve the desired low-friction axial bearing properties.

[0038] Thermoset polyimide (PI) is an example of a liner material that may be selected for properties other than its coefficient of friction. PI tubing is noted for its ability to be formed with tight dimensional tolerances because it is typically formed by building up several layers of cured PI coating around a solid glass core, which is removed by chemical etching. One method of creating a slippery surface on PI tubing is to add a fluoropolymer filler, such as PTFE or FEP, to the PI coating to form one or more low-friction layers at the desired surface(s). Such polyimide/fluoropolymer composite tubing is available from MicroLumen, Inc., Tampa, FL, U.S.A. FIG. 10 illustrates a modified form of the invention wherein the inner surface of liner 145' comprises lubricious coating 150'. Also shown in FIG. 10 is slippery coating 155, which may be applied to core wire 142 in conjunction with, or instead of, a slippery inner surface of liners 145 or 145'. Coating 155 may comprise a thin film of, for example, silicone or a fluoropolymer.

[0039] Another example of a liner material that may be selected for properties other than its coefficient of friction is a block copolymer thermoplastic such as polyethylene block amide (PEBA). Although a slippery coating may be applied to this material, alternatively, its coefficient of friction may be reduced by polymerizing the surface with plasma. Plasma-aided surface functionalization to achieve high lubricity is described in U. S. Patent No. 4,693,799 (Yanagihara *et al.*), and plasma surface modification is available from AST Products, Inc., Billerica, MA, U.S.A. Plasma treated PEBA may be substituted for PTFE in liners to make use of improved physical properties, including the ability to be plastically extruded.

[0040] FIG. 11 depicts a variant of liner 145' disposed within hollow shaft 144. In this example, liner 145' comprises a coiled filament, which may be plastic, metal, or coated or surface-treated forms of either material. The coiled variant may be applied to any of liners 145, 145' or 145", and it provides reduced contact area and concomitantly lower friction as compared to solid tubular lin-

ers. Hollow tube 144 and core wire 142 will only touch coiled liner 145' on helical curvilinear portions of the outer and inner surfaces, respectively. If coiled liner 145' is made with an outer diameter larger than the inner diameter of hollow tube 144, then liner 145' will generally hold itself in assembled position against the inner diameter of hollow tube 144. Similarly, if liner 145" is made as a coil with an inner diameter smaller than the diameter of core wire 142, then liner 145" will generally hold itself in assembled position around core wire 142.

[0041] FIG. 12 depicts a third embodiment of the invention in which filter guidewire 220 incorporates several elements that are similar to the components of filter guidewires 20 and 120. Core wire 242 is disposed within liner 145, which is disposed within hollow shaft 144. Core wire 242 is comprised of proximal section 256 and separate distal section 258, which extends distally from shaft 144. Sliding clearance(s) may be formed between different elongate movable components, as described *supra* and as shown in FIGS. 7, 8 and 9. If liner 145 is fitted against core wire 242, as shown in FIG. 9, then liner 145 will comprise separate proximal and distal sections (not shown) corresponding to core wire proximal section 256 and core wire distal section 258. Flexible tubular tip member 43 is fixed around the distal end of core wire distal section 258. Transition sleeve 270 is slidably disposed about a distal portion of hollow shaft 144 and extends distally there from to a fixed coupling location on tip member 43. Filter 25 is self-expanding and is positioned generally concentrically with the distal portion of shaft 144. Filter distal end 27 is fixedly coupled to transition sleeve 270, and filter proximal end 29 is fixedly coupled to shaft 144 adjacent the distal portion thereof.

[0042] Prior to negotiating vascular anatomy with filter guidewire 220, filter 25 may be collapsed by advancing core wire proximal section 256 within shaft 144 and liner 145 until the distal end of proximal section 256 abuts the proximal end of distal section 258, forming continuous core wire 242. Continued advancement of core wire 242 through shaft 144 and liner 145 will displace tip member 43 distally away from shaft 144. The axial translation of tip member 43 will draw sleeve 270 distally along, but not off of, the distal portion of hollow shaft 144. The relative longitudinal movement of sleeve 270 with respect to shaft 144 causes filter distal end 27 to move away from filter proximal end 29, transforming filter 25 from its expanded configuration to its collapsed configuration. Optionally, filter guidewire 220 may include bends 160 in core wire proximal section 256 (not shown) to provide frictional engagement between core wire 242 and the proximal end of shaft 144. As described *supra*, the optional friction mechanism thus created can hold core wire 242 in a selected axial position within shaft 144, thereby retaining filter 25 in the collapsed configuration.

[0043] Withdrawing core wire proximal section 256 proximally through shaft 144 and liner 145 allows filter 25 to transform itself towards the expanded configura-

tion by drawing filter ends 27, 29 closer together. The self-transformation of filter 25 towards the expanded configuration causes simultaneous proximal movement of sleeve 270, tip member 43 and core wire distal section 258 relative to shaft 144. The self-expansion of filter 25 stops when a) filter 25 reaches its pre-formed expanded configuration, or b) filter 25 encounters a radial constraint, such as apposition with a vessel wall in a patient, or c) filter 25 encounters an axial constraint, such as the proximal end of sleeve 270 contacting filter proximal end 29, as depicted in FIG. 12. After self-expansion of filter 25 has stopped, any further withdrawal of core wire proximal section 256 will cause it to separate from core wire distal section 258, thereby allowing core wire distal section 258, tip member 43, and sleeve 270 to move freely with respect to the distal end of hollow shaft 144. In this configuration, core wire proximal section 256 will not interfere with self-expansion or self-adjustment of filter 25 in its apposition with the vessel wall.

[0044] Transition sleeve 270 may be made of polyimide tubing and may be fixed to tip member 43 and to filter distal end 27 with adhesive, such as cyanoacrylate. The length and mounting position of sleeve 270 are selected such that sleeve 270 always surrounds the distal end of shaft 144, regardless of the configuration and length of filter 25. Sleeve 270 can support core wire 242 across the longitudinal gap between the distal end of shaft 144 and the proximal end of tip member 43. By contributing additional stiffness over its length, sleeve 270 also provides a transition in overall stiffness of filter guidewire 220 adjacent the distal end of shaft 144.

[0045] FIG. 13 depicts a fourth embodiment of the invention in which occluder guidewire 320 incorporates several elements that are similar to the components of filter guidewires 20, 120, and 220. As distinguished from filter guidewire embodiments of the invention, occluder guidewires are typically used to temporarily obstruct fluid flow through the vessel being treated. Any embolic debris trapped upstream of the occluder element may be aspirated using a separate catheter, with or without irrigation of the area. Core wire 342 is disposed within liner 145, which is disposed within hollow shaft 144. Alternatively, liners 145' or 145" may be substituted for liner 145 such that different sliding clearance(s) may be formed between different elongate movable components, as described *supra* and as shown in FIGS. 7, 8 and 9. Flexible tubular tip member 43 is fixed around the distal end of core 342. Transition sleeve 270 is slidably disposed about a distal portion of hollow shaft 144 and extends distally there from to a sliding coupling location on tip member 43. Stop 381 protrudes radially outward from the proximal end of tip member 43, and stop 382 protrudes radially inward from the distal end of transition sleeve 270. Stops 381, 382 interact to prevent the distal end of transition sleeve 270 from sliding proximally off of tip member 43. Stop 381 may comprise a portion of tip member 43, such as one or more enlarged turns at the proximal end of a coil spring. Alternatively, stop 381

may be created with metal or plastic elements, such as solder or polyimide bands. Stop 382 may comprise a portion of transition sleeve 270, such as a rim or neck of reduced diameter formed at the distal end thereof. Alternatively, stop 382 may be created with metal or plastic elements, such as polyimide bands.

[0046] Occluder 325 is self-expanding and is positioned generally concentrically with the distal portion of shaft 144. Occluder 325 may comprise a tubular braid similar to filter 25, which is coated with an elastic material to render it non-porous. Alternatively, occluder 325 may include self-expanding struts (not shown) that support a non-porous elastic membrane, as known to those of ordinary skill in the art. A non-porous coating or membrane may be made from a variety of elastic materials, such as silicone rubber or a thermoplastic elastomer (TPE). Occluder distal end 327 is fixedly coupled to transition sleeve 270, and occluder proximal end 329 is fixedly coupled to shaft 144 proximally adjacent the distal portion thereof.

[0047] In occluder guidewire 320, occluder 325 may be collapsed by advancing core wire 342 through shaft 144 and liner 145, causing tip member 43 to translate within transition sleeve 270 until stop 381 engages stop 382, as shown in FIG. 13. Continued advancement of core wire 342 through shaft 144 and liner 145 will displace tip member 43 distally from shaft 144, drawing sleeve 270 along, but not off of, the distal portion of hollow shaft 144. The relative longitudinal movement of sleeve 270 with respect to shaft 144 causes occluder distal end 327 to move away from occluder proximal end 329, which transforms occluder 325 from its expanded configuration to its collapsed configuration. Reversing the above manipulation, i.e. drawing core wire 342 proximally through shaft 144 and liner 145, permits occluder 325 to expand itself. Self-expansion of occluder 325 will stop when one of several conditions is met, as described above with respect to self-expanding filter 25 of filter guidewire 220. Thereafter, continued withdrawal of core wire 342 will draw tip member 43 proximally within transition sleeve 270, creating axial separation (not shown) between stops 381, 382, thereby allowing the distal end of transition sleeve 270, with stop 382, to slide freely along tip member 43. In this configuration, core wire 342 and tip member 43 will not interfere with self-expansion or self-adjustment of occluder 325 in its apposition with the vessel wall.

[0048] FIG. 13 illustrates the portion of core wire 342 within hollow shaft 144 having a first proximal segment 390, which also extends proximally from hollow shaft 144. First proximal segment 390 is sized to fit slidably within hollow shaft 144, but without sufficient radial clearance for liners 145, 145' or 145". First proximal segment 390 may comprise a major length of core wire 342, such that relatively short core wire distal segment 391 is dimensioned to receive liners 145, 145' or 145". For example, if occluder guidewire 320 is designed for use in coronary arteries, then the overall length of core wire

342 may be about 175 cm, and the length of core wire distal segment 391 may be about 15 to 25 cm. Alternatively, first proximal segment 390 may have a relatively short length such that core wire distal segment 391 and surrounding liners 145, 145' or 145" extend through a major length of hollow shaft 144.

[0049] The transition in diameter between core wire distal segment 391 and first proximal segment 390 may occur as step 398, which can limit the proximal slippage of free-floating liner 145 along core wire 342. Optionally, occluder guidewire 320 may exclude any liner while still incorporating stepped diameter core wire 342 shown in FIG. 13. In such an arrangement, the annular space that would otherwise be occupied by a liner can provide enlarged clearance and accompanying reduced friction between core wire 342 and hollow shaft 144, especially when occluder guidewire 320 is curved through tortuous anatomy. Core wire 342 may also optionally include bends 160 (not shown) located distal to first proximal segment 390.

[0050] In order to steer a distal protection guidewire in accordance with the invention through tortuous vasculature, tip member 43 is typically bent or curved prior to insertion of the device, which should transmit to tip member 43 substantially all of the rotation, or torque applied by the clinician at the proximal end of the device. It is most convenient for the physician to steer the device by grasping and rotating shaft 144, and having such rotation imparted to tip member 43, either directly or through the core wire. In distal protection guidewires of the instant invention, various design features reduce longitudinal friction between the hollow shaft and the core wire. These same friction-reducing features also reduce rotational friction between the hollow shaft and the core wire, which would otherwise be useful in transmitting rotation to steer the device. In filter guidewires 20, 120 and 220, torque is transmissible from shaft 144 to tip member 43 through the braided structure of filter 25, however this action is generally effective only when filter 25 is in the collapsed configuration. In occluder guidewire 320, occluder distal end 327 is slidably connected to tip member 43 through transition sleeve 270 such that torque cannot be transmitted from shaft 144 to tip member 43 through occluder 325.

[0051] It is therefore advantageous, as shown in occluder guidewire 320, to include a torque-transmitting element, such as torque member 384. Torque member 384 can comprise metal or plastic filaments that form a hollow tube of counter wound spirals or a braid. To minimize bulk and stiffness, torque member 384 may include only a single filament in each of the clockwise and counter clockwise winding directions. The proximal end of torque member 384 is bonded to the distal end of shaft 144 and extends distally there from to surround core wire 342 over a relatively short distance. The distal end of torque member 384 is bonded to the proximal end of tip member 43, or to core wire 342 adjacent thereto. The braided, or spirally wound tubular structure of torque

member 384 permits it to transmit rotation forces between shaft 144 and tip member 43, and to do so at any length required to accommodate longitudinal displacement of shaft 144 and tip member 43 during transformation of occluder element 325 between a collapsed configuration and an expanded configuration.

[0052] FIG. 14 illustrates occluder guidewire 320', which incorporates an alternative torque-transmitting element. Core wire distal segment 391' includes flat 386, as may be formed thereon by grinding. Dimple 388 is formed in shaft 144', as by controlled crimping, to extend through an opening in liner 145 and to slidably engage flat 386. Dimple 388 permits limited longitudinal displacement of shaft 144' and core wire 342' during transformation of occluder element 325 between a collapsed configuration and an expanded configuration. Dimple 388 engages with flat 386 to perform as a key and keyway arrangement, transmitting rotation between shaft 144' and core wire 342'.

[0053] In occluder guidewire 320, second proximal segment 392 is located proximally of first proximal segment 390 and has an enlarged diameter approximating the outer diameter of shaft 144. Reinforcement coil 396 surrounds first proximal segment 390 between second proximal segment 392 and the proximal end of hollow shaft 144. Coil 396 has about the same outer diameter as shaft 144, and helps prevent kinking of the portion of first proximal segment 390 that extends from hollow shaft 144. Alternatively, FIG. 14 shows reinforcement coil 396', which is formed as an integral, spirally cut section at the proximal end of shaft 144'. The proximal end of reinforcement coil 396' is bonded to first proximal segment 390, as by adhesive or solder, to effectively form second proximal segment 392. Reinforcement coils 396 and 396' can vary in length to accommodate longitudinal displacement of shaft 144' and core wire 342' during transformation of occluder element 325 between a collapsed configuration and an expanded configuration.

[0054] Third proximal segment 394 is located proximally of second proximal segment 392 and is adapted for engagement to a guidewire extension (not shown), as is well known to those of ordinary skill in the art of guidewires. Examples of guidewire extensions usable with occluder guidewire 320 and other embodiments of the invention are shown in U.S. Patent No. 4,827,941 (Taylor), U.S. Patent No. 5,113,872 (Jahrmarkt *et al.*) and U.S. Patent No. 5,133,364 (Palermo *et al.*)

[0055] To adjust and maintain the relative longitudinal and/or rotational positions of core wires and the surrounding hollow shafts in the various embodiments of the invention, a removable handle device (not shown) of a type familiar to those of skill in the art may be used. Such handle devices can have telescoping shafts with collet-type clamps that grip respectively the core wires and shafts in the various embodiments of guidewire apparatuses according to the present invention. The handle device can also serve as a steering handle, or "torquer" which is useful for rotating steerable-type

guidewires that are incorporated in the instant invention.

[0056] A method of using of a guidewire apparatus of the invention is described as follows. It should be noted that the example described *infra* is unnecessarily limited to a filter guidewire embodiment. Filter guidewire 20, having self-expanding filter 25 and hollow shaft 44 is provided, and advancing core wire 62 through shaft 44 collapses filter 25. With filter 25 in the collapsed configuration, filter guidewire 20 is advanced into the patient's vasculature until filter 25 is beyond intended treatment site 15. Withdrawal of core wire 62 allows filter 25 to expand. With filter 25 deployed into contact with the vessel wall, a therapeutic catheter is advanced over filter guidewire 20 to treatment site 15, and therapy, such as balloon angioplasty, is performed. Any embolic debris generated during the therapy is captured in filter 25. After the therapy is completed, the therapeutic catheter is prepared for withdrawal, as by deflating the balloon, if so equipped. Advancing core wire 62 through shaft 44 collapses filter 25. Finally, filter guidewire 20 and the therapeutic catheter can be withdrawn separately or together, along with collected embolic debris contained within filter 25. If an occluder guidewire of the invention were substituted for a filter guidewire in the above-described method, then aspiration of trapped embolic material would be performed with a separate catheter before collapsing the occluder element.

[0057] One benefit of the structures of filter guidewires 20, 120 and 220 is that guidewire tip member 43 forms a fixed length tip of the device, regardless of the configuration of filter 25. Conversely, in occluder guidewire 320, the tip length changes as occluder distal end 327 slides along tip member 43 during transformation of occluder 325 between expanded and collapsed configurations. The variable tip length of occluder guidewire 320 provides a short tip when occluder 325 is collapsed, but the tip needs to lengthen distally of treatment site 15, if possible, during expansion of occluder 325. During deployment of filter guidewires 20, 120 and 220, the distal tip position of the device can remain fixed relative to treatment site 15. This is accomplished by the user holding core wires 42, 142 or 242 anchored relative to the patient, while applying tension to shafts 44 or 144 in the proximal direction. Filter 25 can be maintained in a collapsed configuration by a friction mechanism including bends 160, or by applying proximal tension to shafts 44, 144, thus holding filter proximal end 29 apart from filter distal end 27. Releasing the tension on shafts 44, 144, or advancing them manually, allows filter 25 to expand by filter proximal end 29 translating distally towards filter distal end 27. During this filter deployment, however, the distal tip does not need to move relative to filter 25 or treatment area 15.

[0058] While the invention has been particularly shown and described with reference to the preferred embodiments thereof, it will be understood by those skilled in the art that various changes in form and detail may be made there in without departing from the spirit

and scope of the invention. For example, the invention may be used in any intravascular treatment utilizing a guidewire where the possibility of loosening emboli may occur. Although the description herein illustrates angioplasty and stent placement procedures as significant applications, it should be understood that the present invention is in no way limited to those environments.

Claims

1. A guidewire apparatus comprising:

an elongate hollow shaft having an inner wall and proximal and distal ends;
a core wire movably disposed within the shaft and having a distal end extending there from;
a generally tubular protection element having a distal end fixed adjacent the core wire distal end and a proximal end fixed adjacent the shaft distal end, wherein relative longitudinal movement between the distal and proximal ends of the protection element accompanies a transformation of the protection element between a collapsed configuration and an expanded configuration; and
a liner interfitted between the core wire and the shaft inner wall, the liner having an inner surface and an outer surface, wherein at least one of the surfaces has a low coefficient of friction.

2. The guidewire apparatus of claim 1, wherein the liner inner surface has a low coefficient of friction and is sized to provide a radial clearance with the core wire.

3. The guidewire apparatus of claim 1, wherein the liner outer surface has a low coefficient of friction and is sized to provide a radial clearance with the shaft inner wall.

4. The guidewire apparatus of claim 1, wherein the liner inner and outer surfaces both have low coefficients of friction and the liner is sized such that radial clearances exist between the liner inner surface and the core wire, and between the liner outer surface and the shaft inner wall.

5. The guidewire apparatus of claim 1 further comprising a flexible tip member fixed about the core wire distal end.

6. The guidewire apparatus of claim 1, wherein a core wire proximal end extends from the shaft proximal end.

7. The guidewire apparatus of claim 6, wherein one or more bends are formed in a portion of the core wire

within the shaft proximal end, the one or more bends providing frictional engagement with the shaft inner wall and being capable of stopping proximal slippage of the liner along the core wire.

8. The guidewire apparatus of claim 6, wherein a portion of the core wire proximal end extending from the hollow shaft is enlarged in diameter.

9. The guidewire apparatus of claim 8, wherein a reinforcement coil surrounds a segment of the core wire between the enlarged portion and the shaft proximal end.

10. The guidewire apparatus of claim 6, wherein the shaft proximal end is fixedly attached to the core wire and a portion of the hollow shaft adjacent the shaft proximal end is spirally cut to form a variable-length reinforcement coil surrounding a segment of the core wire.

11. The guidewire apparatus of claim 1, wherein the protection element is a filter.

12. The guidewire apparatus of claim 1, wherein the protection element is an occluder.

13. The guidewire apparatus of claim 5 further comprising a torque-transmitting element capable of transmitting rotation forces from the hollow shaft to the core wire.

14. The guidewire apparatus of claim 13, wherein the torque-transmitting element is a filamentous tube having proximal and distal ends and a variable length to permit longitudinal displacement between the shaft and the core wire, the tube disposed about the core wire distal end at a location extending from the shaft distal end towards the tip member, the tube proximal end being fixed to the shaft distal end and the tube distal end fixedly connected to a proximal end of the tip member.

15. The guidewire apparatus of claim 13, wherein the torque-transmitting element is a filamentous tube having proximal and distal ends and a variable length to permit longitudinal displacement between the shaft and the core wire, the tube disposed about the core wire distal end at a location extending from the shaft distal end towards the tip member, the tube proximal end being fixed to the shaft distal end and the tube distal end fixedly connected to the core wire adjacent to a proximal end of the tip member.

16. The guidewire apparatus of claim 13, wherein the torque-transmitting element comprises a flat formed on the core wire and a corresponding dimple formed in the hollow shaft, the dimple being en-

gaged with the flat to permit longitudinal displacement between the shaft and the core wire, while transmitting rotation forces from the hollow shaft to the core wire.

17. A guidewire apparatus comprising:

an elongate hollow shaft having an inner wall and a distal portion having a distal end;
a core wire movably disposed within the shaft and having a distal end extending there from and a flexible tip member fixed about the core wire distal end;
a transition sleeve having a distal end and being slidably disposed about the shaft distal portion and extending distally there from to surround a proximal portion of the tip member;
a generally tubular protection element having a distal end fixed about the transition sleeve and a proximal end fixed to the shaft proximally of the shaft distal portion, wherein relative longitudinal movement between the distal and proximal ends of the protection element accompanies a transformation of the protection element between a collapsed configuration and an expanded configuration; and
a liner interfitted between the core wire and the hollow shaft, the liner having inner and outer surfaces, wherein at least one of the surfaces has a low coefficient of friction.

18. The guidewire apparatus of claim 17, wherein the transition sleeve distal end is fixed about the tip member proximal portion.

19. The guidewire apparatus of claim 17, wherein the transition sleeve distal end is slidably disposed about the tip member proximal portion, and a pair of stop elements prevents the transition sleeve distal end from sliding proximally off of the tip member.

20. The guidewire apparatus of claim 17, wherein the protection element is self-expandable to the expanded configuration.

21. The guidewire apparatus of claim 17, wherein the hollow shaft comprises metal tubing.

22. The guidewire apparatus of claim 21, wherein the metal tubing comprises nitinol.

23. The guidewire apparatus of claim 17, wherein the liner comprises polymeric tubing.

24. The guidewire apparatus of claim 23, wherein the polymeric tubing comprises polyimide.

25. The guidewire apparatus of claim 24, wherein the

at least one low-friction surface comprises a layer of polyimide having a fluoropolymer filler.

26. The guidewire apparatus of claim 23, wherein the at least one low-friction surface comprises plasma-aided surface modification.

27. The guidewire apparatus of claim 26, wherein the polymeric tubing comprises polyethylene block amide copolymer.

28. The guidewire apparatus of claim 17, wherein the liner comprises a coiled filament.

29. The guidewire apparatus of claim 17 wherein a slippery coating is disposed on the core wire.

30. The guidewire apparatus of claim 17, wherein the protection element is a filter.

31. The guidewire apparatus of claim 17, wherein the protection element is an occluder.

32. A guidewire apparatus comprising:

an elongate hollow shaft having a length, an inner wall and a distal portion;
a liner disposed within substantially the length of the hollow shaft and having inner and outer surfaces, wherein at least one of the surfaces has a low coefficient of friction;
a core wire having separate distal and proximal sections slidably disposed within the liner, the core wire proximal section being adapted to abut and push the core wire distal section distally within the liner, the distal core wire section having a distal end extending from the shaft distal portion and having a flexible tip member fixed there about;
a transition sleeve being slidably disposed about and extending from the shaft distal portion, the sleeve having a distal end coupled about the tip member; and
a generally tubular, self-expanding protection element having a distal end coupled about the transition sleeve and a proximal end coupled to the shaft proximally of the shaft distal portion, wherein relative longitudinal movement between the distal and proximal ends of the protection element accompanies a transformation of the protection element between a collapsed configuration and an expanded configuration.

33. The guidewire apparatus of claim 32 wherein the sleeve distal end is fixedly coupled about the tip member.

34. The guidewire apparatus of claim 32 wherein the

- sleeve distal end is slidably coupled about the tip member and restrained by stop members from sliding proximally off of the tip member.
35. The guidewire apparatus of claim 32 wherein the hollow shaft has an outer diameter of about 0.36 mm (0.014 inch). 5
36. The guidewire apparatus of claim 32 wherein the hollow shaft has an inner diameter of about 0.23 mm (0.009 inch). 10
37. The guidewire apparatus of claim 32 wherein the core wire distal and proximal sections have a diameter of about 0.15 mm (0.006 inch). 15
38. The guidewire apparatus of claim 32 wherein the liner has an outer diameter of about 0.22 mm (0.0088 inch). 20
39. The guidewire apparatus of claim 38 wherein the liner has an inner diameter of about 0.18 mm (0.0069 inch).
40. The guidewire apparatus of claim 32, wherein the protection element is a filter. 25
41. The guidewire apparatus of claim 32, wherein the protection element is an occluder. 30
42. A guidewire apparatus comprising:
- an elongate hollow shaft having an inner wall and proximal and distal ends;
- a core wire having a portion movably disposed within the hollow shaft and having a distal end extending there from, the portion of the core wire within the hollow shaft having a distal segment and a first proximal segment, the diameter of the first proximal segment being larger than the diameter of the core wire distal segment; and 35
- a generally tubular protection element having a distal end fixed adjacent the core wire distal end and a proximal end fixed adjacent the shaft distal end, wherein relative longitudinal movement between the distal and proximal ends of the protection element accompanies a transformation of the protection element between a collapsed configuration and an expanded configuration. 40 45 50
43. The guidewire apparatus of claim 42 further comprising a liner interfitted between the core wire distal segment and the shaft inner wall, the liner having inner and outer surfaces, wherein at least one of the surfaces has a low coefficient of friction. 55
44. The guidewire apparatus of claim 43, wherein a step in diameter between the core wire distal segment and the core wire first proximal segment is capable of stopping proximal slippage of the liner along the core wire.
45. The guidewire apparatus of claim 42, wherein core wire distal segment has a length that is substantially shorter than the length of the core wire first proximal segment.
46. The guidewire apparatus of claim 42, wherein core wire first proximal segment has a length that is substantially shorter than the length of the core wire distal segment.

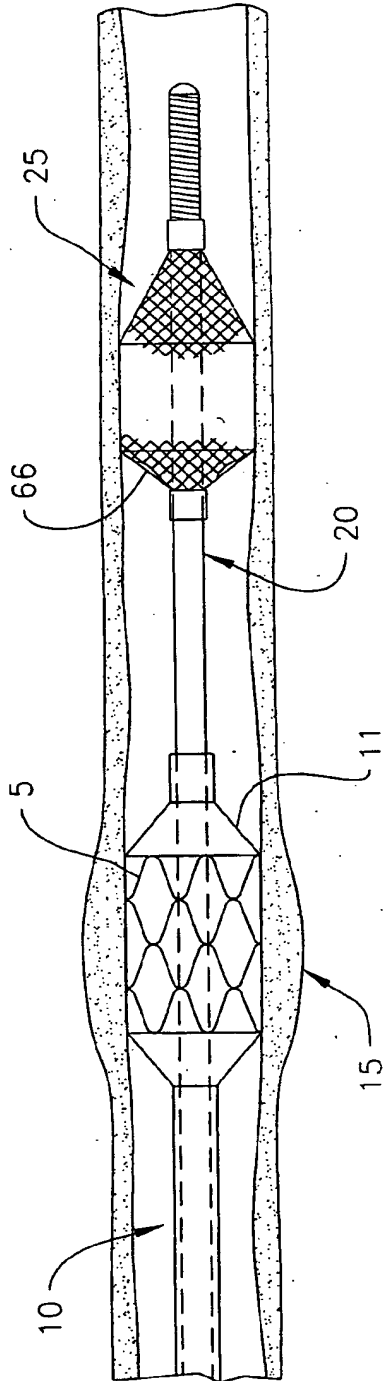


FIG. 1

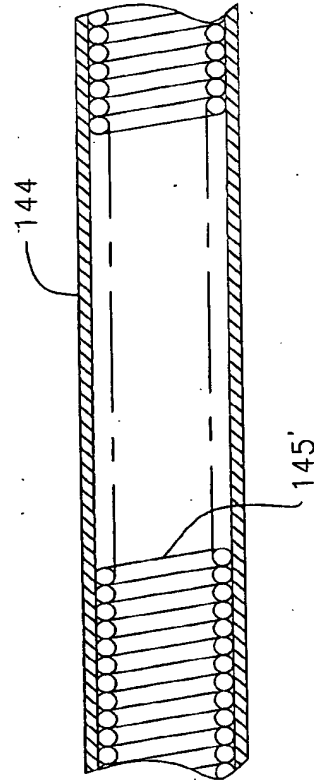


FIG. 11

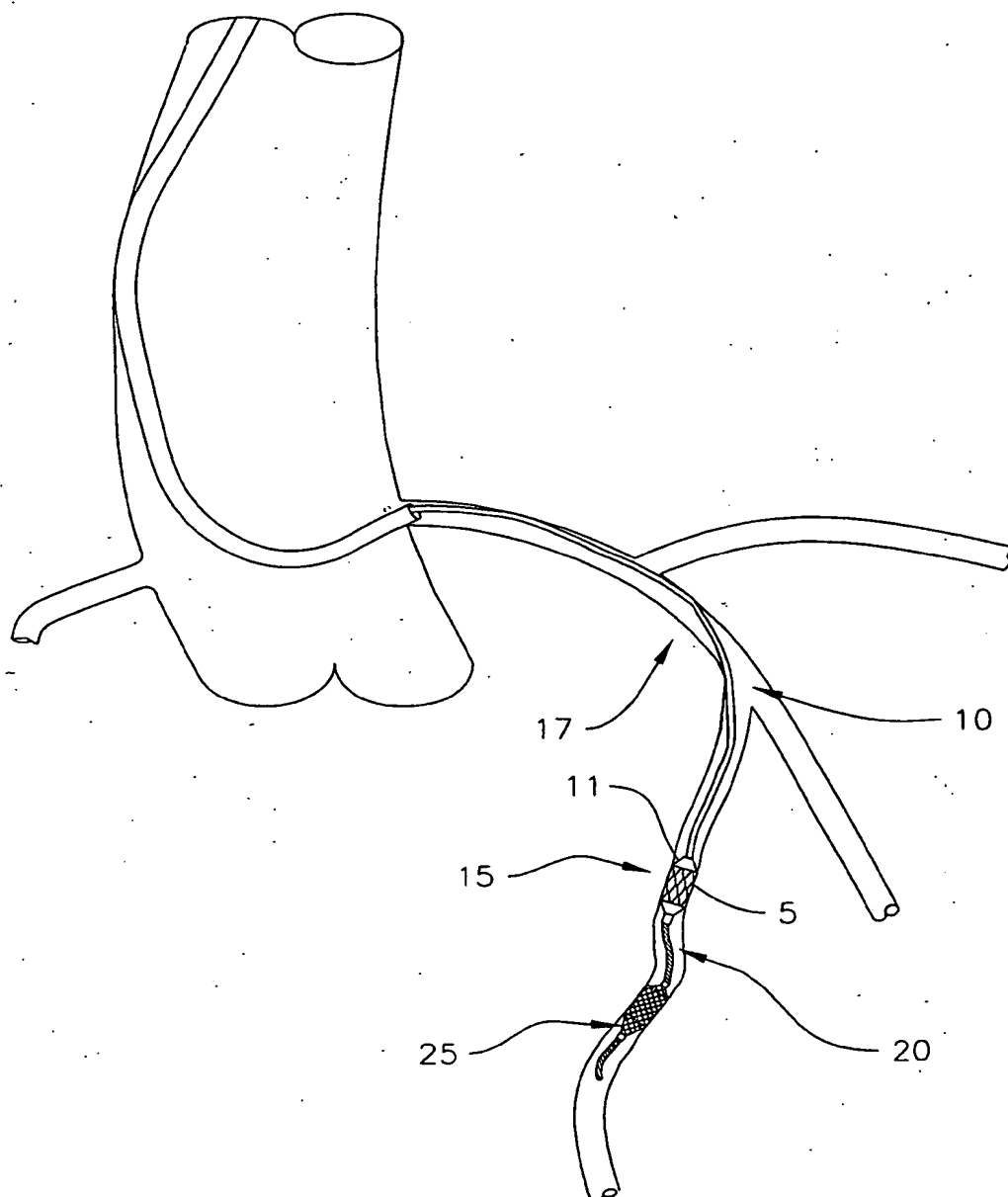


FIG. 2

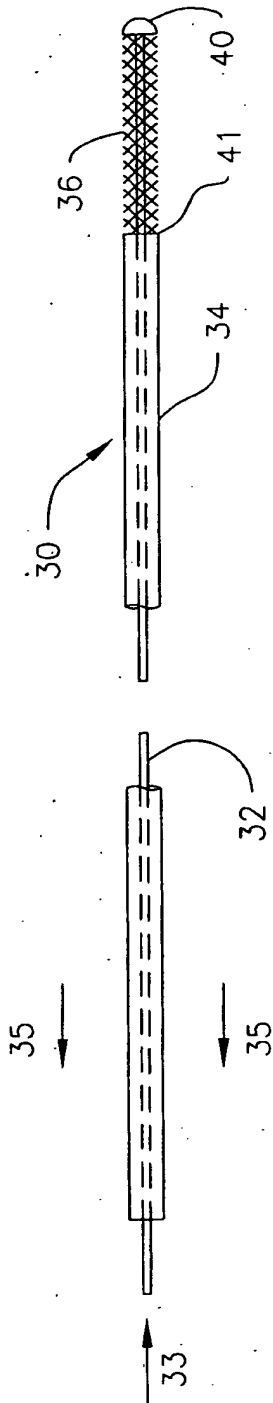


FIG. 3
(PRIOR ART)

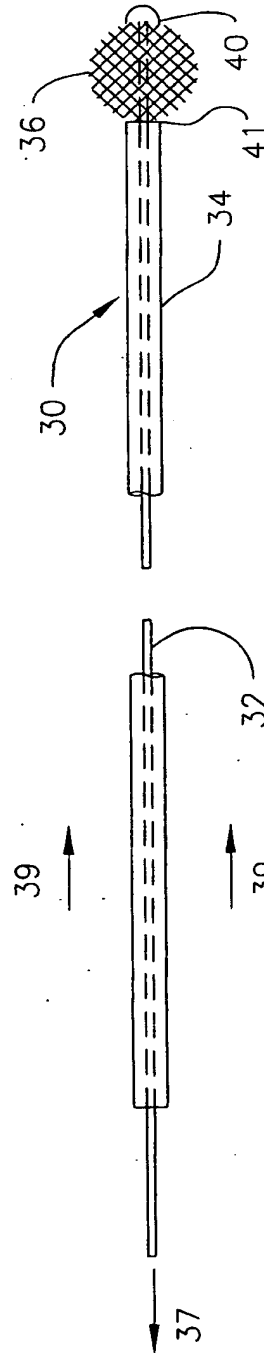


FIG. 4
(PRIOR ART)

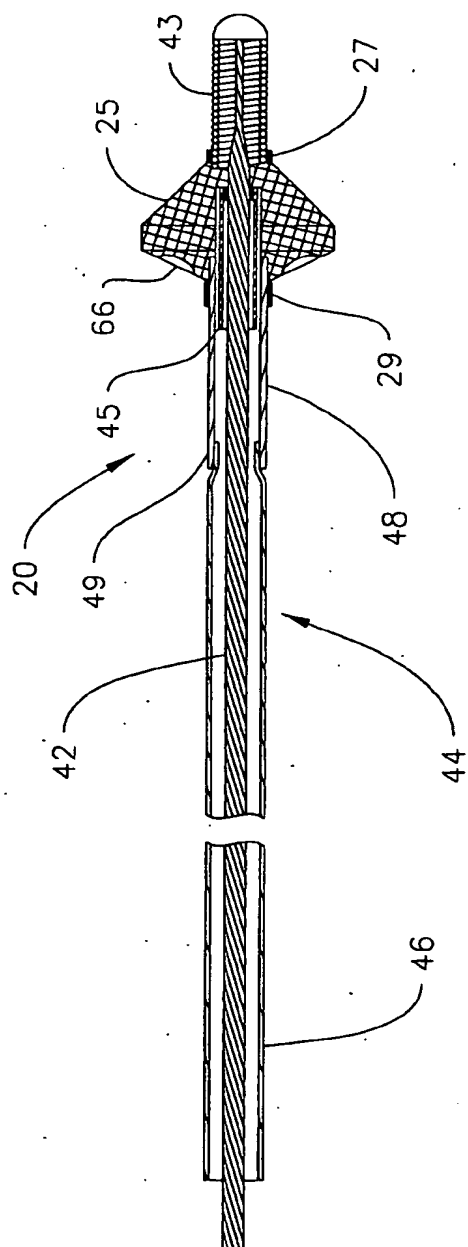


FIG. 5

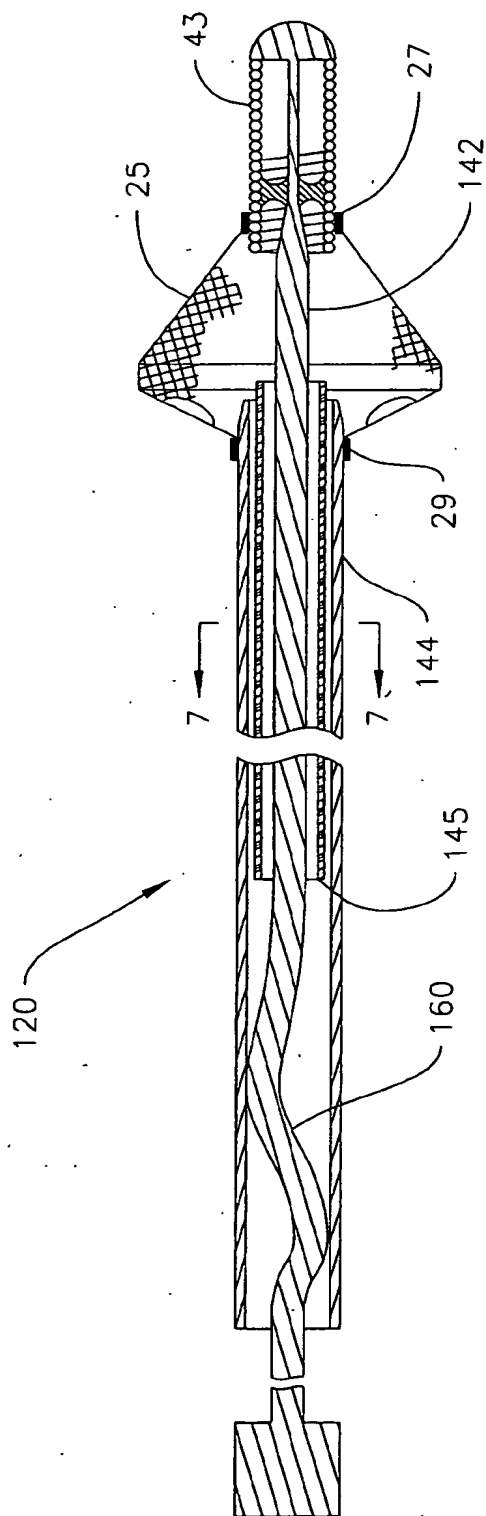


FIG. 6

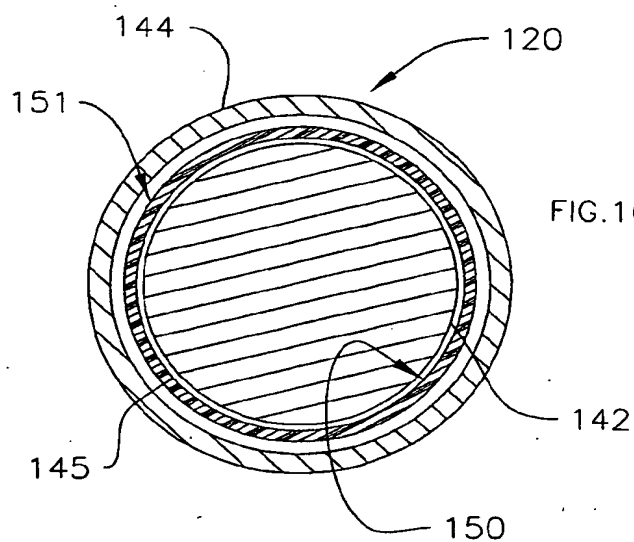


FIG. 7

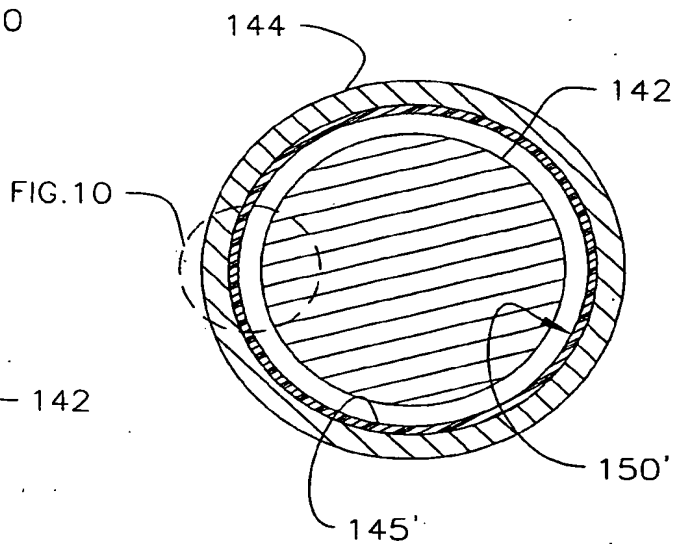


FIG. 8

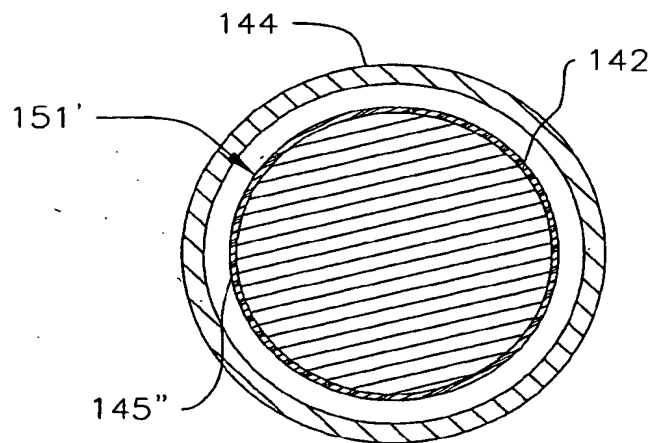


FIG. 9

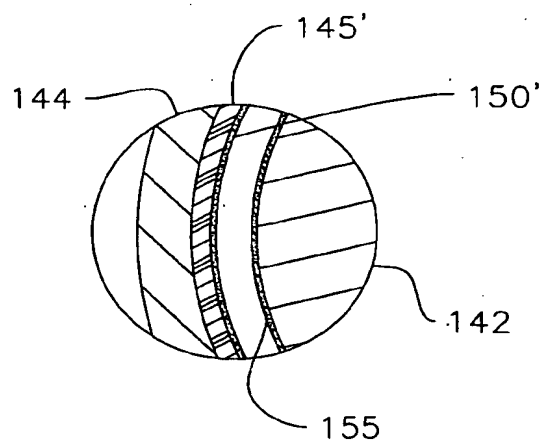


FIG. 10

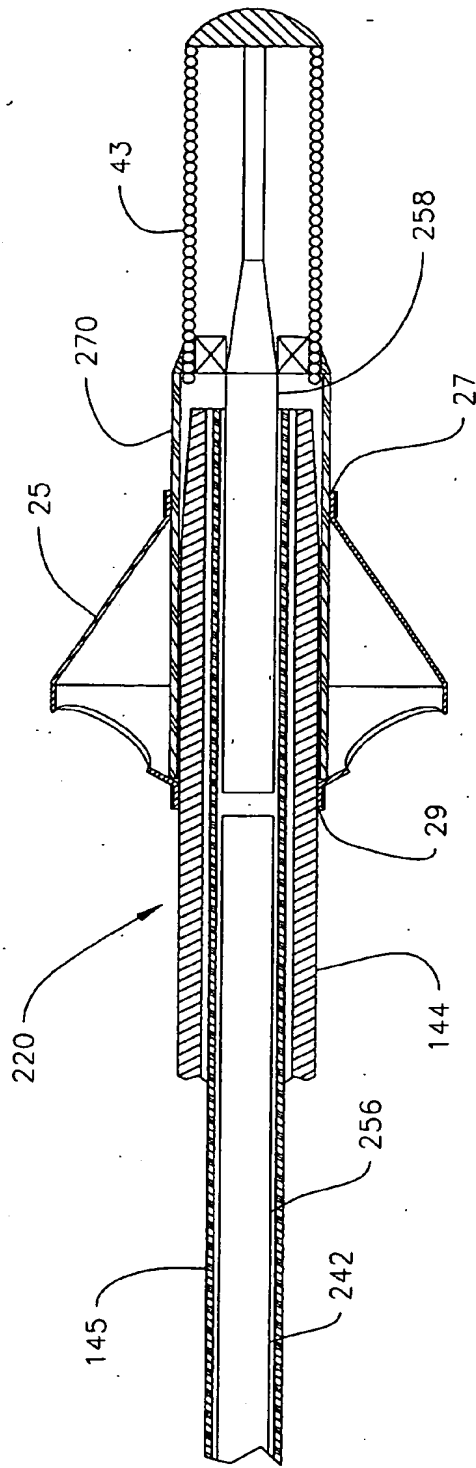


FIG. 12

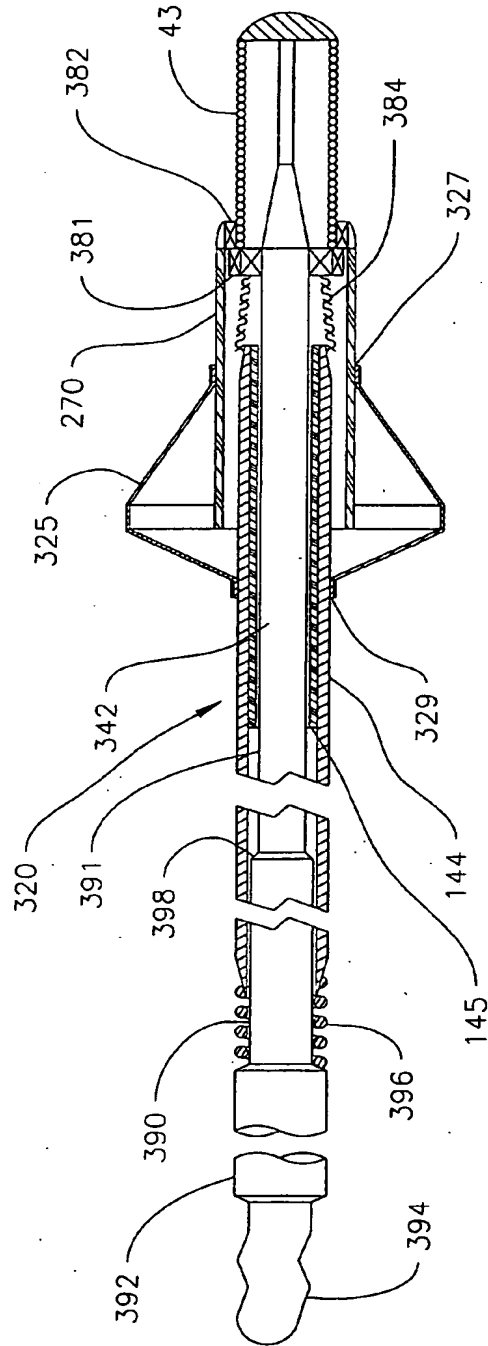


FIG. 13

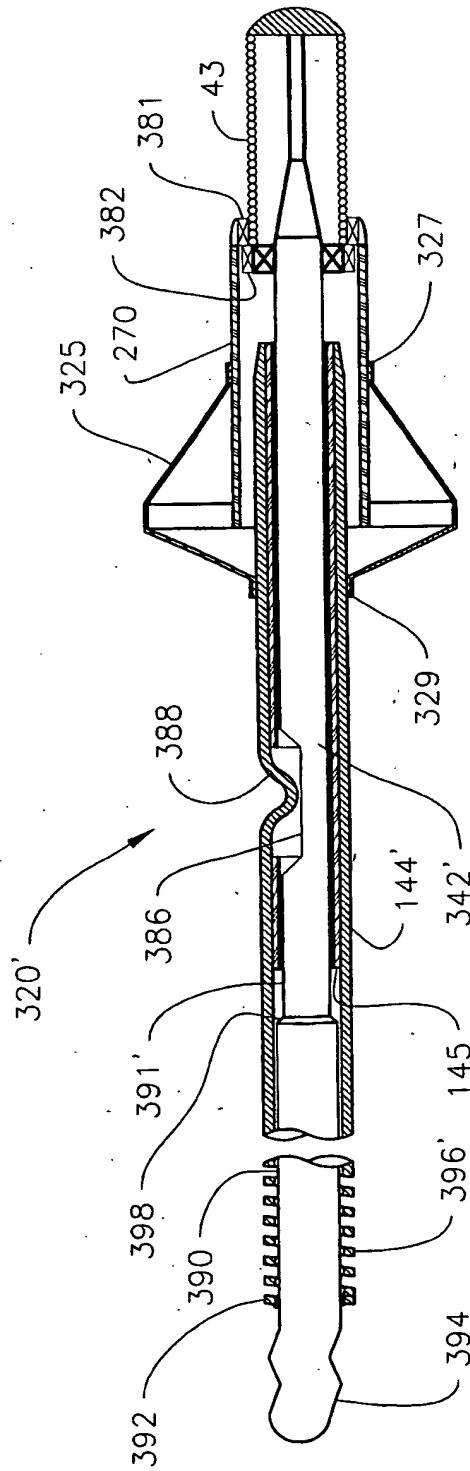


FIG. 14



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(54) **Temporary distal embolic protection device**

(57) A guidewire apparatus for use during percutaneous catheter interventions, such as angioplasty or stent deployment. A protection element comprising a filter or an occluder is mounted near the distal end of a steerable guidewire, which guides a therapeutic catheter. The guidewire apparatus comprises a hollow shaft

movably disposed about a core wire and, optionally, a slippery liner interfitted there between. The shaft and core wire control relative displacement of the ends of the protection element, causing transformation of the protection element between a deployed configuration and a collapsed configuration.

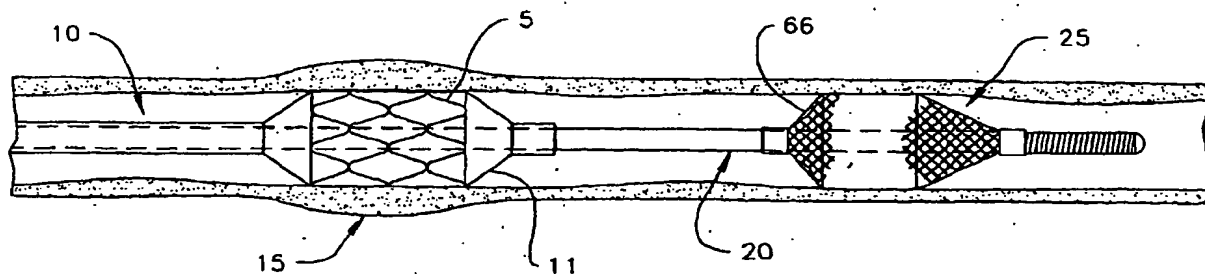


FIG. 1

EP 1 344 502 A3



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EUROPEAN SEARCH REPORT

Application Number
EP 03 00 5072

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.7)
A	WO 01 45592 A (PERCUSURGE, INC.) 28 June 2001 (2001-06-28) * page 11, line 1 - page 12, line 2; figures 8A-8C *	1	A61F2/01
A	EP 1 127 556 A (SCION CARDIO-VASCULAR, INC.) 29 August 2001 (2001-08-29) * abstract; figures *	1	
			TECHNICAL FIELDS SEARCHED (Int.Cl.7)
			A61F
The present search report has been drawn up for all claims			
Place of search The Hague		Date of completion of the search 15 May 2003	Examiner Smith, C.
CATEGORY OF CITED DOCUMENTS		T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application I : document cited for other reasons & : member of the same patent family, corresponding document	
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EPO FORM 1503 03.82 (P04C01)



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Application Number

EP 03 00 5072

CLAIMS INCURRING FEES

The present European patent application comprised at the time of filing more than ten claims.

- ☐ Only part of the claims have been paid within the prescribed time limit. The present European search report has been drawn up for the first ten claims and for those claims for which claims fees have been paid, namely claim(s):
- ☐ No claims fees have been paid within the prescribed time limit. The present European search report has been drawn up for the first ten claims.

LACK OF UNITY OF INVENTION

The Search Division considers that the present European patent application does not comply with the requirements of unity of invention and relates to several inventions or groups of inventions, namely:

see sheet B

- ☐ All further search fees have been paid within the fixed time limit. The present European search report has been drawn up for all claims.
- ☐ As all searchable claims could be searched without effort justifying an additional fee, the Search Division did not invite payment of any additional fee.
- ☐ Only part of the further search fees have been paid within the fixed time limit. The present European search report has been drawn up for those parts of the European patent application which relate to the inventions in respect of which search fees have been paid, namely claims:
- ☒ None of the further search fees have been paid within the fixed time limit. The present European search report has been drawn up for those parts of the European patent application which relate to the invention first mentioned in the claims, namely claims:

1-16



European Patent
Office

LACK OF UNITY OF INVENTION
SHEET B

Application Number
EP 03 00 5072

The Search Division considers that the present European patent application does not comply with the requirements of unity of invention and relates to several inventions or groups of inventions, namely:

1. claims: 1-16

Guidewire apparatus with liner having a low coefficient of friction

2. claims: 17-31

Guidewire apparatus with a transition sleeve

3. claims: 32-41

Guidewire apparatus having core wire with separate distal and proximal sections

4. claims: 42-46

Guidewire apparatus having core wire with transitional diameter

**ANNEX TO THE EUROPEAN SEARCH REPORT
ON EUROPEAN PATENT APPLICATION NO.**

EP 03 00 5072

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report. The members are as contained in the European Patent Office EDP file on
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15-05-2003

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			WO 0145592 A1	28-06-2001
EP 1127556	A	29-08-2001	US 6277138 B1	21-08-2001
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